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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,502	07/03/2003	Richard M. Beane	07917-160001 / UMMC 02-09	4420
26161 7590 03/19/2008 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER BLATT, ERIC D	
			ART UNIT 3734	PAPER NUMBER
			MAIL DATE 03/19/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/613,502	Applicant(s) BEANE ET AL.	
	Examiner Eric Blatt	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 15-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10-10-2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-14 in the reply filed on 2-11-2008 is acknowledged.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the hand-drawn figures are informal and it is difficult to clearly identify individual elements and the spatial relations between therebetween. This is particularly the case in Figures 3a-3c and 5. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 8 and 9, claims 8 and 9 recite element “the handle.” While a “handle assembly” has antecedent basis in the claim language, it is unclear whether the handle and the handle assembly are identical elements. Said claims also recite “the flexible hollow tube.” Multiple hollow tubes have antecedent basis in the claim language. Neither is recited to be flexible.

Regarding claims 12 and 13, said claims recite element “the handle.” While a “handle assembly” has antecedent basis in the claim language, it is unclear whether the handle and the handle assembly are identical elements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poloyko et al. (US 5,741,276) in view of Poncet et al. (US 5,254,130).

Regarding claims 1, 2, and 6-8 Poloyko discloses a surgical suture placement device (Figures 2 and 3) comprising a handle assembly comprising a plunger 62, an elongated hollow outer tube 36, a suturing assembly having a needle 52 secured to a distal end of the outer tube 36, and a thin flexible actuating rod 64 running between the handle assembly and the needle 52. The suturing assembly also comprises a holding

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member (track containing needle therein), also considered to be a needle guide having suture aperture 48, that removably holds the needle 52, and a needle cover 38.

Thus, Poloyko discloses all elements of claims 1, 2, 6-8, 12, and 13 except for the suturing assembly being rotatably secured to the outer tube and being actuated by the outer tube, inner tube, rod, mechanism as claimed. Poncet discloses a similar minimally invasive device (Figure 1) comprising a functional distal portion 11 that is rotatably secured to a outer tube 7, a flexible hollow inner tube 5 located within the outer tube 7, and a thin flexible rod 15 arranged within the hollow inner tube 5 configured to actuate the functional distal portion 11. This configuration allows the functional distal portion of the device to be separately actuated, rotated, and deflected relative to the longitudinal axis. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by providing the suturing assembly such that it is rotatably secured to the outer tube, and providing a hollow inner tube containing the flexible actuating rod such that the suturing assembly may be separately actuated, rotated, and deflected relative to the longitudinal axis of the device as taught by Poncet.

Regarding claims 3-5, Poloyko does not teach that the needle is hollow and has an open, sharp tipped distal end with rounded edges such that a suture may extend from an aperture on a proximal surface of the needle to an opening at the distal end of the needle. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide such a needle since such needles were notoriously old and well known to be used for suturing.

Regarding claim 9, Poloyko does not teach that there is a spring that biases the needle plunger into an extended position and the needle into a retracted position. It was well known to provide a spring on such plunger actuating mechanisms in order to bias the plunger into an extended position and the device into a non-actuated position. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by providing a spring that biases the needle plunger into an extended position and the needle into a retracted position in order to prevent the needle from projecting from the distal end without the surgeon intending for the needle to do so.

Regarding claims 10 and 11, Poncet teaches that the functional distal end may be angled away from the longitudinal axis of the hollow outer tube. (Figure 1) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by having the suture assembly be angled away from the longitudinal axis of the outer tube in order to allow the suture assembly to access a wider variety of anatomies. It would have been obvious to have said angle be a 45 degree angle since the court has held that it is within the knowledge of a person skilled in the art to determine optimal range for the function of a device.

Regarding claims 12 and 13, the handle assembly of Poloyko is rotatable. The embodiment shown in Figure 1 of Poncet teaches that the outer tube rotated in order to rotate the functional distal portion. In the embodiment shown in Figure 2, however, Poncet teaches that the inner tube 19 may be used to control rotation of the functional distal portion, and that said inner tube 19 may extend proximally beyond the outer tube

such that the proximal end acts as a handle to allow the user to rotate said "handle", thereby rotating the hollow inner tube and the functional distal portion as a unit.

(Column 6, Line 61 through Column 7, Line 8) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by having the handle concurrently rotate the hollow inner tube and suture assembly as a unit since it was a known mechanism by which to control rotation a functional distal portion as taught by Poloyko.

Claim 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Poloyko et al. (US 5,741,276) in view of Poncet et al. (US 5,254,130) as applied to claims 1-13 above and further in view of Djurovic (US 6,315,784).

Regarding claim 14, Poloyko in view of Poncet teaches all elements of claim 14 as previously discussed except for a suture holder attached to the needle guide wherein the needle guide is secured between the needle cover and the suture holder. The suture material of Poloyko is fed from a supply outside the body through the flexible actuating rod and to the suturing assembly. Djurovic teaches that a suture holder containing a supply of suture material may instead be attached at the distal end of a suturing device. (Figure 1) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Poloyko by providing a suture holder within the suture assembly since Djurovic teaches that this was a known alternative to feed suturing material to the needle. Since the needle cover 38 is the outer housing of the suture assembly and the needle guide is the track containing the

needle therein, by positioning the suture holder within the suture assembly as taught by Djurovic, the needle guide would be secured between the suture holder and at least some portion of the needle cover.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Blatt
571-272-9735

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/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731